

K051665

3 510(k) Summary

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| Name of Firm: | Synthes Spine 1302 Wrights Lane East West Chester, PA 19380 |
| 510(k) Contact: | Susan Lewandowski Senior Regulatory Affairs Specialist Telephone: 610-719-5712 Facsimile: 610-719-5102 |
| Trade Name: | Synthes Vectra-T System |
| Common Name: | Cervical Plating Instrumentation |
| Device Product Code and Classification: | KWQ - 888.3060 - Spinal Intervertebral Body Fixation Orthosis Class II |
| Substantially Equivalent Devices: | K971883 - Synthes CSLP-SS (Cervical Spine Locking Plate - Small Stature), cleared October 16, 1997 K030866 - CSLP (added DDD indication), cleared April 18, 2003 K050451 - Synthes Vectra System, cleared March 24, 2005 |
| Device Description: | <p>The Synthes Vectra-T System consists of one-level to four-level plates with cancellous and cortex fixed-angle and variable-angle screws. The plate attaches to the anterior portion of the vertebral body of the cervical spine (C2-C7). The plate uses a translating mechanism for the screw carriage to slide to accommodate for bone graft resorption. There is a removable spacer that holds the screw carriage in place during screw placement.</p> <p>The plates and screws are manufactured from Titanium Aluminum Niobium (Ti-6Al-7Nb), the same as K050451 Vectra System. The plate clip is manufactured from Elgiloy (40Co-20Cr-16Fe-15Ni-7Mo), the same as K050451 Vectra System.</p> |
| Intended Use / Indications for Use: | <p>Synthes Vectra-T System is intended for anterior plate and screw fixation of the cervical spine (C2-C7).</p> <p>Synthes Vectra-T System is indicated for the following: Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by</p> |

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| | history and radiographic studies), Spondylolisthesis, Trauma (i.e., fractures or dislocations), Spinal Stenosis, Tumors (primary and metastatic), Failed previous fusions, Pseudoarthrosis, Deformity (i.e., scoliosis, kyphosis, and/or lordosis) |
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SEP - 9 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Susan Lewandowski
Senior Regulatory Affairs Specialist
Synthes Spine
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K051665

Trade/Device Name: Synthes Vectra-T System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: June 21, 2005
Received: June 22, 2005

Dear Ms. Lewandowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson *for*
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2 Indications for Use Statement

Traditional 510(k) Premarket Notification

Indications for Use Statement

510(k) Number
(if known):

K 051665

Device Name: Synthes Vectra-T System

Indications for Use: Synthes Vectra-T System is intended for anterior plate and screw fixation of the cervical spine (C2-C7).

Synthes Vectra-T System is indicated for the following:

- Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fractures or dislocations)
- Spinal Stenosis
- Tumors (primary and metastatic)
- Failed previous fusions
- Pseudoarthrosis
- Deformity (i.e., scoliosis, kyphosis, and/or lordosis)

Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use X
(21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Neil P. O'Neil for MDM
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K051665
CONFIDENTIAL
Synthes Vectra T System

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